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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,944	05/31/2006	Martin F. Bachmann	1700.0670000	2922

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
10/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,944	BACHMANN ET AL.	
	Examiner	Art Unit	
	EMILY M. LE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2006 and 18 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,10,14-16,33,34,41,47,48,50,52-55,57,63 and 64* is/are pending in the application.

4a) Of the above claim(s) *57 and 63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 5, 10, 14-16, 33-34, 41, 47-48, 50, 52-55, and 64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/02/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 07/18/2008 is acknowledged. The traversal is on the ground(s) that the inventions listed as Groups I-II have a shared special technical feature. This is not found persuasive. As detailed in the previous office action, the shared technical feature between the inventions listed as Groups I-II is not a shared special technical feature for said technical feature does not provide a contribution over the prior art. To support this, the Office cited the teachings of Bachmann et al. to demonstrate that said shared technical feature does not provide a contribution over the prior art. In the absence of a contribution over the prior art, said shared technical feature is not a shared special technical feature. Without a share special technical feature, the inventions listed as Groups I-II lack unity with one another.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

2. Claims 3-4, 6-9, 11-13, 17-32, 35-40, 42-46, 49, 51, 56 and 58-62 are cancelled. Claim 64 is added. Claims 1-2, 5, 10, 14-16, 33-34, 41, 47-48, 50, 52-55, 57 and 63-64 are pending. Claims 57 and 63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07/18/2008. Claims 1-2, 5, 10, 14-16, 33-34, 41, 47-48, 50, 52-55, and 64 are under examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "said palindromic sequence" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1-2, 5, 10, 14-16, 33-34, 41, 47-48, 50, 52-55, and 64 rejected under 35 U.S.C. 102(a) as being anticipated by Bachman.[1]

The claims are directed to a composition comprising a virus like particle (VLP) with an immunostimulatory nucleic acid packaged within the VLP, an antigen mixed with or coupled to the VLP, and at least one toll-like receptor (TLR) ligand, wherein the ligand and immunostimulatory nucleic acid activate different TLR. Claim 2, which depends on claim 1, requires the ligand to be mixed with said VLP. Claim 5, which depends on claim 1, requires the ligand be a ligand for TLR 4. Claim 10, which

[1] Bachmann et al. U.S. PreGrant Publication No. 2003/0099668 A1, published May 29, 2003.

depends on claim 1, requires that the immunostimulatory nucleic acid be an unmethylated CpG oligonucleotide. Claim 14, which depends on claim 10, requires that the oligonucleotide is part of a palindromic sequence. Claim 15, which is interpreted to depend on claim 14, requires the palindromic sequence to be GACGATCGTC. Claim 16, which depends on claim 10, requires the oligonucleotide to comprise the sequence: GGGGGGGGGGGACGATCGTCGGGGGGGGGG. Claim 33, which depends on claim 1, requires the immunostimulatory nucleic acid to be an unmethylated CpG oligonucleotide and that the ligand be a ligand for any one of TLR 1-8 and 10-11. Claim 34, which depends on claim 33, requires that the ligand be a ligand for TLR 4. Claim 64, which depends on claim 34, requires that the ligand be LPS or a derivative thereof. Claim 41, which depends on claim 1, requires that the VLP comprises recombinant proteins or fragments thereof, of a RNA-phage, wherein said RNA-phage is bacteriophage QB or bacteriophage AP205. Claims 47 and 52, which depends on claim 1, requires the antigen to be selected from the group consisting of pollen, dust, dust mite, fungal, mammalian epidermal, feather insect, food, hair, saliva and serum extracts. Claim 48, which depends on claim 1, requires the antigen to be selected from the group consisting of viruses, bacteria, parasites, prions, tumors, self-molecules, non-peptidic hapten molecules, allergens and hormones. Claim 50, which depends on claim 1, requires the antigen be a tumor antigen selected from the group consisting of Her2, GD2, EGF-R, CEA, CD52, human melamona protein gp100, human melamona protein melan-A/MART-1, tyrosinase, NA17-A nt protein, MAGE-3 protein, p53 protein, HPV16 E7 protein, an analogue of any of the listed antigens and antigenic fragments of any of

the listed antigens. Claim 53, which depends on claim 1, requires the antigen to be an allergen selected from the group consisting of trees, grasses, house dust, house dust mite, aspergillus, animal hair, animal feather, bee venom, animal products and plant products. Claim 54, which depends on claim 1, requires the antigen be selected from the group consisting of bee venom phospholipase A2, ragweed pollen Amb a 1, birch pollen Bet v I, white faced hornet venom 5 Dol mV, house dust mite Der p 1, house dust mite Der f 2, house dust mite Der 2; dust mite Lep d; fungus allergen Alt a 1; fungus allergen Asp f 1; fungus allergen Asp f 16 and peanut allergens. Claim 55, which depends on claim 1, requires the antigen to be a cytotoxic T cell epitope, a Th cell epitope or a combination of at least two of said epitopes, wherein said at least two epitopes are bound directly or by way of a linking sequence.

Bachmann et al. teaches a composition comprising a virus like particle (VLP) with an immunostimulatory nucleic acid packaged within the VLP, an antigen mixed with or coupled to the VLP, and at least one toll-like receptor (TLR) ligand, wherein the ligand and immunostimulatory nucleic acid activate different TLR. [Entire disclosure and claims 1-2, 5, 21, 57-59 and 63, in particular.] The ligands that Bachmann et al. teaches are ligands for TLR 4, including lipopolysaccharide and lipoteichonic acids. Bachmann et al. also teaches mixing the ligand with the VLP. The immunostimulatory nucleic acid Bachmann et al. teaches include unmethylated CpG oligonucleotides comprising the sequence: GGGGGGGGGGGACGATCGTCGGGGGGGGGG, which has the palindromic sequence GACGATCGTC. The VLP that Bachmann et al. teaches

comprise recombinant proteins or fragments thereof, of a RNA-phage, wherein said RNA-phage is bacteriophage QB or bacteriophage AP205.

The antigens that Bachman et al teaches include Her2,GD2, EGF-R, CEA, CD52, human melanoma protein gp100, human melanoma protein melan-A/MART-1, tyrosinase, NA 17-A nt protein, MAGE-3 protein, p53 protein, HPV16 E7 protein, allergens such as dust mite, bee venom phospholipase A2, birch pollen Bet v I, prison, viruses, bacterial, tumors, self-molecules, parasites, non-peptidic hapten molecules, allergens, hormones; cytotoxic T cell epitopes, and Th cell epitopes, or a combination of at least of the two epitopes, wherein said at least two epitopes are bound directly or by way of a linking sequence.

In the instant case, Bachmann et al. teaches the claimed invention. Therefore, Bachmann et al. anticipates the claimed invention.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-2, 5, 10, 14-16, 33-34, 41, 47-48, 50, 52-55, and 64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of copending Application No. **10/465811**, which published as U.S PreGrant Publication No. 2004/0005338. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instantly claimed invention is directed to a composition comprising a virus like particle (VLP) with an immunostimulatory nucleic acid packaged within the VLP, an antigen mixed with or coupled to the VLP, and at least one toll-like receptor (TLR) ligand, wherein the ligand and immunostimulatory nucleic acid activate different TLR.

The invention claimed in the copending patent application is also directed to a composition comprising a virus like particle (VLP) with an immunostimulatory nucleic acid packaged within the VLP, an antigen mixed with or coupled to the VLP, and at least one toll-like receptor (TLR) ligand, wherein the ligand and immunostimulatory nucleic acid activate different TLR.

In the instant case, while claim 4 of the copending application does not readily identify that members of the listed Markush group are all TLR ligands, however, it is well known that the listed members are all TLR ligands.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-2, 5, 10, 14-16, 33-34, 41, 47-48, 50, 52-55, and 64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. **10/243739**, which published as U.S PreGrant Publication No. 2003/0091593. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instantly claimed invention is directed to a composition comprising a virus like particle (VLP) with an immunostimulatory nucleic acid packaged within the VLP, an antigen mixed with or coupled to the VLP, and at least one toll-like receptor (TLR) ligand, wherein the ligand and immunostimulatory nucleic acid activate different TLR.

The invention claimed in the copending patent application is also directed to a composition comprising a virus like particle (VLP) with an immunostimulatory nucleic

acid packaged within the VLP, a tumor antigen bound to the VLP, and imidazoquinoline compounds.

The difference between the claims: claim 1 of the copending patent application is directed to a species of antigen, tumor antigen, whereas, the broadest claims of the instant patent application is directed to a genus of antigens. Tumor antigens are encompassed by the genus of antigens claimed in the instant patent application. In the instant case, the tumor antigen species anticipates the genus of antigens instantly claimed.

The other difference is, claim 1 of the copending application does not readily identify imidazoquinoline compounds are TLR ligands, however, it is well known in the art that said compounds are TLR ligands.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

/E. M. L./